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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/219,935	12/23/1998	JOHN BROWSE	BB-1036-B	4143

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E I DU PONT DE NEMOURS AND COMPANY  
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4417 LANCASTER PIKE  
WILMINGTON, DE 19805

EXAMINER
MCELWAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
07/30/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

09/219,935

**Applicant(s)**

BROWSE ET AL.

**Examiner**

Elizabeth F. McElwain

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,20-27 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,20-24,26,27 and 29-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_.

### DETAILED ACTION

Claims 1, 20-27 and 29-33 are pending.

Claim 25 is withdrawn as drawn to a non-elected invention.

Claims 1, 20-24, 26, 27 and 29-33 are examined on the merits.

After reconsideration of the claims, finality has been withdrawn and the following rejection is set forth.

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 20-24, 26, 27 and 29-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid fragment encoding a plant plastid or microsomal enzyme which catalyzes the formation of a double bond between carbon positions 3 and 4 numbered from the methyl end of a fatty acyl chain, wherein said enzyme has an amino acid identity of 50% or greater to a polypeptide having an amino acid sequence of any one of SEQ ID NOS: 2, 5, 7, 9, 11, 13, 15 or 17 or to a fragment of said sequences having at least 425 base pairs, does not reasonably provide enablement for any part of any one of said sequences which is useful in antisense inhibition or sense suppression of endogenous desaturase activity in a transformed plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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and/or use the invention commensurate in scope with these claims. The claims are drawn to an isolated nucleic acid sequence that may be any part of a sequence having as little as 50% identity to any of SEQ ID NOS: 2, 5, 7, 9, 11, 13, 15 or 17 that is useful in antisense inhibition or sense suppression of endogenous desaturase activity. However, the specification only discloses use of the full length sequences or to sequences that are at least 425 base pairs (at page 111, line 17 of the specification).

It has been well established that sequence homology is not sufficient to predict function of encoded sequences. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and “overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions” (the last sentence of the first paragraph of page 248). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph). In addition, Smith et al (Nature Biotechnology 15:1222-1223, November 1997) teach that “there are numerous cases in which proteins of very different functions are homologous” (page 1222, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating that “most homologs must have different molecular and cellular functions” (see the second full paragraph of the second column of page 132, for example). Furthermore, Borks (TIG 12, 10:425-427, October 1996) teaches numerous problems with the sequence databases that can result in the misinterpretation of sequence data.

More specifically, identification of related sequences that will encode enzymes having a particular activity is particularly problematic in the enzymes involved in modifying fatty acids,

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and cannot be determined merely by similarity of DNA or amino acid sequences. Van de Loo et al teach that sequences encoding fatty acid hydroxylase activity are highly similar to other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). In fact, Broun et al teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least). In addition, De Luca teaches that modifying plant biosynthetic pathways by transforming plants with genes encoding enzymes involved in said pathway is highly unpredictable (see the paragraph bridging the columns on page 225N, for example), and that "on many occasions desired goals have been impossible to achieve" (see the last paragraph on page 228N). Therefore, both the identification of other genes encoding fatty acid desaturase activity, and the modification of plant lipid composition by transforming a plant with said gene or a portion of said gene are highly unpredictable.

Therefore, if sequences are identified only by similarity to other sequences that are known to encode fatty acid desaturase activity, one cannot conclude that these other sequences also encode enzymes having fatty acid activity and more specifically it is highly unpredictable what the effect in a plant would be of expression of any part of the multitude of sequences encompassed by the claims. The specification only provides the example of a fragment having at least 425 base pairs of the sequences recited in the claims. The specification does not teach analysis of the effects of any other fragments in a transformed plant. Given the high level of similarity of fatty acid desaturases to other fatty acid modifying enzymes, it is unclear what endogenous genes will be suppressed by the multitude of parts of nucleic acid sequences encompassed by the claims. The specification does not teach how to use the multitude of nucleic acid fragments encompassed by the claims, and it would require undue experimentation by one

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skilled in the art to sort through the parts of the multitude of claimed sequences to identify those that would function in the manner claimed which have been taught how to use in the specification.

Given the unpredictability of identifying sequences portions of fatty acid desaturase coding sequences for modifying the lipid composition of a plant, as evidenced above; the lack of guidance in the specification for identifying and characterizing partial sequences other than the 425 bp sequence described in the specification that will function in antisense suppression or cosuppression of the endogenous desaturase when transformed into a plant ; the lack of working examples of other partial sequences and their effect in a plant; and the breadth of the claims which encompass portions of an isolated nucleic acid fragment encoding a plant plastid or microsomal enzyme which catalyzes the formation of a double bond between carbon positions 3 and 4 numbered from the methyl end of a fatty acyl chain, wherein said enzyme has an amino acid identity of 50% or greater to a polypeptide having an amino acid sequence of any one of SEQ ID NOS: 2, 5, 7, 9, 11, 13, 15 or 17, and use of said genes to modify a fatty acid; it would require undue experimentation by one skilled in the art to make and use the invention as broadly claimed.

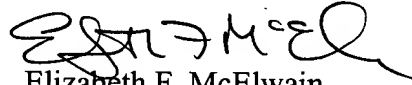
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Elizabeth F. McElwain  
Primary Examiner  
Art Unit 1638

EFM